REMARKS

Claims 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 are pending and stand rejected. New claim 81 is added herein. Support for claim 81 is provided by the specification at, e.g., page 82, Example 2 and Figure 2. Accordingly, no new matter is added by way of this amendment. Applicants respectfully request entry of the new claim and reconsideration in view of the following remarks. Claims 49, 54, 56-58, 63, 66, 72, 75, and 79-81 are now pending.

Rejection Under 35 U.S.C. § 101

Claims 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 are rejected under 35 U.S.C. § 101, because the claimed invention allegedly is not supported by either a specific, substantial, and credible asserted utility or a well established utility. Briefly, the Examiner asserts that there is no nexus between the expression of the 254P1D6B (SEQ ID NO:1) (i.e., the 284 amino acid SSH DNA probe) in cancerous tissues and the expression of the claimed full length sequences having SEQ ID NOs: 3, 5 and 7. Thus, the Examiner concludes there is no objective evidence that the claimed sequences can be used as cancer markers or possess any property reported for SEQ ID NO:1. In addition, the Examiner cites the art for the proposition that one of skill in the art cannot anticipate the biological activity or tissue distribution of protein variants based on the wild type protein or a single protein isoform. Thus, the Examiner asserts that the various aspects of the claimed invention lack patentable utility. Applicants traverse the rejections for reasons of record, as well as at least the following.

Under 35 U.S.C. § 101, a patent may be granted to "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter." An invention may be useful for "any particular practical purpose (i.e., it has a "specific and substantial utility)." MPEP § 2107. When making a rejection for an alleged lack of utility, the Office must make a *prima facie* showing that the claimed invention lacks utility and it must provide sufficient evidence to support the basis of that *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224 (CCPA 1975); MPEP § 2107.2. By contrast, Applicants need only provide one credible assertion of specific and substantial

utility for each claimed invention to satisfy the utility requirement. MPEP § 2101 (II)(B). Alternatively, the utility requirement can be met by showing well established utility. MPEP § 2107 II(A).

The Examiner has acknowledged that evidence of differential expression might serve as the basis for use of the claimed polynucleotides as a diagnostic for disease. *See* Office action at page 3. Applicants respectfully submit that the specification provides evidence of differential expression of the claimed 254P1D6B sequences in *at least* cancerous prostate versus normal prostate tissue, sufficient to establish utility.

The invention is useful for diagnosing prostate cancer

As previously noted by the Applicants, the full length variants of 254P1D6B, including *inter alia* the polynucleotides having SEQ ID NOs:2, 4, and 6, were identified using the SSH DNA sequence having SEQ ID NO:1, in a subtraction consisting of a prostate cancer xenograft LAPC-9AD[2] minus prostate cancer xenograft LAPC-9AD. *See* specification at, e.g., pages 82, Example 2. Thus, the Applicants have demonstrated that the claimed polynucleotide sequences are present in cancerous prostate tissue. Applicants respectfully submit that the fact that the full length sequences of SEQ ID NOs:2, 4, and 6 were identified from a prostate cancer xenograft subtraction experiment indicates that they were over-expressed in prostate cancer versus normal prostate, as that is the basis of the subtraction experiment. *See, e.g.*, Diatchenko et al., *Proc. Natl. Acad. Sci.*(1996), 93:6025-6030 (attached as Exhibit A). Because the claimed sequences were identified using the SSH DNA sequence of SEQ ID NO:1 as a probe, it is also apparent that this SSH DNA probe is capable of identifying the claimed polynucleotide sequences having SEQ ID NOs:2, 4, and 6 if they are, in fact, present in a sample.

As shown in Figure 15, multiple tissue northern blots were probed using the same SSH DNA sequence (SEQ ID NO:1) to determine the expression of 254P1D6B in normal tissues. As shown in Figure 15, no expression of 254P1D6B was observed in normal prostate tissue. *See* Figure 15, right-hand panel, lane 3.

It has already been established that the SSH DNA sequence (SEQ ID NO:1) will hybridize with the claimed sequences if present. Thus, it is clear from the data in Figure 15 that the claimed sequences having SEQ ID NOs:2, 4 and 6 are not present in normal prostate tissue, at least not in detectable amounts. Taken together, the data provided in Example 2 and in Figure 2 and Figure 15 demonstrate that the claimed sequences are differentially over-expressed in cancerous versus normal prostate tissue.

The Applicants have asserted that the claimed genes (254P1D6B) and their encoded proteins are useful in diagnostic methods for detecting cancers that overexpress 254P1D6B, including, e.g., prostate, lung and ovarian cancers. As described above, Applicants have provided evidence that the claimed sequences are differentially over-expressed in *at least* cancerous versus normal prostate tissue, and thus could be used as diagnostic or prognostic markers for prostate cancer.

The claimed invention has a specific, substantial and credible utility

Applicants respectfully submit that the asserted utility is specific, substantial and credible. "[A] specific utility is particular to the subject matter claimed and would not be applicable to a broad class of invention." *In re Fisher*, 421 F.3d 1365, 1372 (*citing* MPEP §2107.01). The claims relate to polynucleotides having SEQ ID NO:2, 4, and 6, which differ from each other by a single nucleotide residue, and to the polypeptides having SEQ ID NOs:3, 5, and 7 encoded by these sequences, which differ from each other by a single amino acid residue. Thus, the asserted utility is specific, as the claimed subject matter relates to a narrow genus of closely related sequences.

In addition, the asserted utility is substantial, in that it defines a "real world" or "practical" use for the invention, as diagnostic or prognostic markers for prostate cancer. *See* MPEP §2107.01. This use provides a genuine public benefit. The Examiner is reminded that the present lack of an immediately available commercial diagnosis for cancer based on the claimed polypeptide does not render the invention useless under *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966).

Moreover, the asserted utility is credible. The credibility of an asserted utility is assessed from the perspective of a person of ordinary skill in the art. MPEP § 2101 (II)(B). A number of prostate specific cancer markers are used as diagnostics for prostate cancer. In view of these products, those of ordinary skill in the art would recognize that the presently asserted utility is credible.

The Office has not stated a *prima facie* case

When making a rejection for an alleged lack of utility, the Office must make a *prima facie* showing that the claimed invention lacks utility and it must provide sufficient evidence to support the basis of that *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224 (CCPA 1975); MPEP § 2107.2. The Applicants' asserted utility carries the presumption of correctness and the Examiner has failed to meet the initial burden in challenging the utility of the claimed protein. The purpose of detecting various cancers with markers such as the claimed proteins is neither inherently unbelievable nor implausible, and the Examiner has not raised sufficient evidence to demonstrate otherwise.

Applicants have provided sufficient evidence to support the asserted utility

In a recent non-precedential decision, the Board of Patent Appeals and Interferences held that microarray data demonstrating mRNA overexpression in cancerous tissues compared to non-cancerous tissues was sufficient to establish a specific and substantial utility for the claimed polypeptide as a cancer marker. *Ex parte Audrey Goddard, Paul J. Godowki, Austin L. Gurney, Victoria Smith, and William I. Wood* (Appeal 2006-1469, Application No. 10/123,212, decided April 30, 2007). A copy of this decision is enclosed herewith as Exhibit B.

Applicants respectfully submit that the data provided by Applicants, and described in detail in Example 4 and Figures 14-17, is analogous to the data shown in *Ex parte Goddard*, which the Board found sufficient to establish utility. Thus, Applicants respectfully submit that sufficient evidence has been provided to satisfy the utility requirement.

The threshold for utility is not high under 35 U.S.C. § 101; an invention is useful if it is merely capable of providing some identifiable benefit. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 51 U.S.P.Q.2d 1700, 1702 (Fed Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). The Applicants have provided a credible, specific and substantial utility, and this is all that is required to satisfy the utility requirement. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the "how to use" prong of the enablement requirement. Specifically, the Examiner asserts that because the invention allegedly lacks either a specific, substantial and credible asserted utility or a well-established utility, a person of skill in the art would not know how to use the claimed invention. Applicants traverse the rejections.

In view of the discussion above, Applicants have more than carried their burden to demonstrate that the claimed subject matter is supported by a credible, substantial, and specific utility. Accordingly, Applicants respectfully request that the present rejection of the claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 511582008100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 9, 2008

Respectfully submitted,

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